

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/854,140	SCHIFFER ET AL.	
	Examiner Sally A Sakelaris	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to March 7 2003.
2.  The allowed claim(s) is/are 1 and 37-45.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a)  The translation of the foreign language provisional application has been received.
6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8.  CORRECTED DRAWINGS must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>5'03</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.              | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                         |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance        |
|  | 9 <input type="checkbox"/> Other   |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows to place claims in condition for allowance:

1. A method of determining predisposition of a subject to a recurrent unipolar depressive disorder, said method comprising determining in a biological sample of a subject, a human kainate receptor subunit G1uR7 allelic genotype, said genotype being homozygosity for a thymine containing nucleotide at position 928 (928T/T), wherein the parents of said subject are T/G heterozygous at position 928 (928T/G)[.] and wherein the presence of the homozygosity for thymine at the 928 position indicates that the subject is predisposed to recurrent unipolar depressive disorder.
2. A method of determining predisposition of a subject to a recurrent unipolar depressive disorder, said method comprising determining in a biological sample from a subject, a human kainate receptor subunit GluR7 allelic phenotype, said phenotype being homozygosity for a serine at amino acid position 310 (310 Ser/Ser), wherein the parents of said subject are heterozygous at position 310, said heterozygosity being 310 Ser/Ala[.] and wherein the presence of the homozygosity for a serine at amino acid position 310 indicates that the subject is predisposed to recurrent unipolar depressive disorder.
3. A method of determining predisposition of a subject to a bipolar II depressive disorder, said method comprising determining in a biological sample of a subject, a human kainate receptor subunit GluR7 allelic genotype, said genotype being homozygosity for a guanine containing nucleotide at position 928 (928G/G), wherein the parents of said subject are T/G heterozygous at position 928 (928T/G)[.] and wherein the presence of the homozygosity for a guanine at the 928 position indicates that the subject is predisposed to bipolar II depressive disorder.
4. A method of determining predisposition of a subject to bipolar II depressive disorder, said method comprising determining in a biological sample of a subject, a human kainate receptor subunit G1uR7 allelic phenotype, said phenotype being homozygosity for alanine at amino acid position 310 (310 Ala/Ala), wherein the parents of said subject are heterozygous at position 310 said heterozygosity being 310 Ser/Ala[.] and wherein the presence of the homozygosity for an alanine at amino acid position 310 indicates that the subject is predisposed to bipolar II depressive disorder.

It is further noted that the title has been amended to read:

--KAINATE RECEPTOR SUBUNIT GLUR7 POLYMORPHISMS FOR DETERMINING  
PREDISPOSITIONS TO RECURRENT UNIPOLAR AND BIPOLAR II DEPRESSIVE  
DISORDERS--

**THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE:**

The present invention is found to be allowable subject matter as its presentation of a method of determining predisposition of a subject to recurrent unipolar and bipolar II depressive disorders through the allelic genotypes of 928T/T and 928G/G respectively and the phenotypes 310 Ser/Ser and 310 Ala/Ala respectively of the human kainite receptor subunit GluR7 represents a contribution over the prior art that lacks any such determination method.

The closest prior art made of record is as follows:

Schiffer et al. teach unequal expression of allelic kainate receptor GluR7 mRNAs in human brains. The prior art reference teaches that the human kainate receptor GluR7 gene contains a thymine (T)/guanine (G) nucleotide variation that determines a serine or alanine at position 310 in the extracellular region of GluR7 receptor subunits. However, the reference does not teach the association of these nucleotide variations with recurrent unipolar depressive disorder nor bipolar II depressive disorder (The Journal of Neuroscience, December 15, 2000, 20(24): 9025-9033).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 6:00AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

*Sally Sakelaris*

5/27/2003

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER